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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,059	12/14/2005	William Marshall Stark	056646-5024	2559
9629 7590 01/22/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 31 DAYS		MAIL DATE 01/22/2007	DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/529,059	Applicant(s) STARK ET AL.	
	Examiner Iqbal H. Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group, I claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 101 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, II claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 102 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, III claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 105 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, IV claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 107 and a catalytic domain peptide and a DNA binding domain, and a kit.

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Group, V claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 117 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, VI claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 121 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, VII claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 124 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, VIII claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 89 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, IX claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 92 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, X claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 103 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, XI claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 2 and a catalytic domain peptide and a DNA binding domain, and a kit.

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Group, XII claim(s) 1-14, 18-42, 46-59, 67-68, drawn to an isolated polypeptide a serine recombinase, hybrid recombinase mutated at position 56 and a catalytic domain peptide and a DNA binding domain, and a kit.

Group, XIII claim(s) 15-17 and 69, drawn to polynucleotide encoding a polypeptide serine recombinase and a kit.

Group, XIV claim(s) 43-45, drawn to polynucleotide encoding a polypeptide hybrid recombinase.

Group, XV claim(s) 60-62, drawn to polynucleotide encoding a polypeptide catalytic domain of serine recombinase.

Group, XVI claim(s) 63, drawn to a method for identifying a hyperactive mutant serine recombinase catalyzing site-specific DNA recombination of recombining DNA comprising contacting first DNA sequence and second DNA sequence with serine recombinase.

Group, XVII claim(s) 64-66, drawn to a method of recombining DNA comprising contacting first DNA sequence and second DNA sequence with serine recombinase.

For each inventions I-XVII above, election of species from one of the following is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-XVII **and** one of the species (A) – (N).

(A). protein of Tn3 resolvase.

(B). protein of Sin recombinase.

(C). protein of y6 resolvase.

(D). protein of Tn21 resolvase.

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- (E). protein of R resolvase.
- (F). protein of ISXc5 recombinase.
- (G). protein of Gin resolvase.
- (H). protein of Hin recombinase.
- (I). protein of Mathanococcus jannaschii resolvase.
- (J). protein of 15667 recombinase.
- (K). protein of ccrA1 resolvase.
- (L). protein of tN4451 recombinase.
- (M). protein of TP901-1 resolvase.
- (N). protein of OC31 recombinase.

2. The inventions listed as Groups I - XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The polynucleotide encoding a polypeptide of Group XII-XV and polypeptide of Group I-XII are each unrelated and chemically distinct entities. The only shared technical feature of these groups is that they all relate to polynucleotide encoding a polypeptide serine recombinase. However, this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2 as it does not define a contribution over the art. Arnold et al. teach a serine recombinase Tn3 resolvase and a mutant G101S and its corresponding DNA molecule. (Mutants of Tn3 resolvase which do not require accessory binding sites for recombination activity, EMBO J. 1999 Mar 1; 18(5): 1407-14, see IDS). Thus, a DNA encoding a serine recombinase protein does not make contribution over the prior art. Therefore, it lacks special technical feature.

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3. A method of identifying a hyperactive mutant serine recombinase of Group XVI does not share any “special technical feature” with Group XIII-XV as the polynucleotides of Group XIII-XV are neither made nor used by the method of Group XVI.

4. A method of recombining DNA of Group XVII does not share any “special technical feature” with Group I-XII as the polynucleotides of Group I-XII are neither made nor used by the method of Group XVII.

5. The methods of Groups XVI-XVII do not have unity of invention with each other, as each method comprises unrelated steps, use different products and produce different effects.

6. In the instant case the different nucleotides encoding proteins of Group (A)-(N), which are polypeptides having recombinase activity, do not have special technical feature among each other because they all represent structurally different polypeptides and polynucleotide encoding them. As mentioned above, a DNA encoding a recombinase Tn3 resolvase protein is known in the art and does not make contribution over the prior art. Therefore, they all lack special technical feature.

37 CFR 1.475 does not provide for multiple products and/or methods within a single application. Therefore, inventions of Group I - XVII lack unity of invention.

This application contains claims directed to the patentably distinct 16-peptide species: presented in claim 36. The species lack special technical feature because each of the variants or peptides having distinct structure and distinct function and part of Tn3 resolvase, which is known in the art. Thus, they lack special technical feature.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

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held to be allowable.

Applicant is required, in reply to this action, to **elect a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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